



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

VIA FEDERAL EXPRESS

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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

Ref: Customs Entry No.: 406-030637-4 (XXX-0038607-9)
Product: Fresh Eggplants / Line Item #004/001
Fresh Squash / Line Item #006/001

WARNING LETTER

FLA-01-86

September 11, 2001

Mr. Walter Vasquez, President
Feedom Fresh, Inc.
8901 NW 33rd Street
Suite 100
Miami, Florida 33172

Dear Mr. Vasquez:

The Food and Drug Administration (FDA), on August 21, 2001, attempted to examine a shipment of fresh eggplants and squash in accordance with our Notice of FDA Action, dated August 19, 2001. The shipment was offered for import (imported) into the United States by your firm on August 18, 2001, under Customs' Entry Number 406-0306367-4. During our visual examination we noted that [REDACTED] cases ([REDACTED] pounds) out of the original [REDACTED] cases of the eggplants and [REDACTED] cases ([REDACTED] lbs) out of the original [REDACTED] cases of squash were already distributed without a FDA release. Reportedly, these [REDACTED] cases of produce were brought back to your facility on or about August 24, 2001.

On August 27, 2001, we returned to your facility to verify the return of the [REDACTED] cases of eggplants and the [REDACTED] cases of squash previously distributed, and to verify that the entry was still held intact. Our examination noted that the products and the number of cases noted as missing on August 21, 2001, were still noted to be missing. There were [REDACTED] pounds of product missing, and the vice president of your firm stated in an affidavit that some of the product had been sold to several customers in the Miami and Broward County areas. Not holding an entry intact pending a FDA release is a violation of 21 CFR Section 1.90. This Section requires the importer to hold an imported article in tact, pending a release notice from FDA.

Failure to promptly correct this situation and prevent future premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs Service,

such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

We will be requesting that U.S. Customs Service order redelivery of the 270 pounds which were distributed without a FDA release. Failure to redeliver the missing portion to Customs custody may result in a penalty action at a later date.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent recurrence. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Carlos W. Hernandez, Compliance Officer, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a stylized flourish extending from the end.

Emma R. Singleton
Director, Florida District

cc: Thomas Winkowski
Port Director
U. S. Customs Service
P. O. Box 02-580
Miami, Florida 33102-5280